Version 5 – Updated February 20, 2021

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AGENDA

All times are Eastern (EST UTC-5)
View Start Time on World Clock

DAY ONE: Wednesday, March 3, 2021

7:45 – 8:05

Administrative Overview

Brenda Stodart
CAPT, USPHS
Director, Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER

8:05 – 8:20

Welcome

Lawrence Yu
Director
Office of New Drug Products (ONDP)
Office of Pharmaceutical Quality (OPQ) | CDER

Your SBIA Hosts for Day One

Forest "Ray" Ford, Jr.
CAPT, USPHS, *Pharmacist*
DDI | OCOMM | CDER

Lisa Misevicz
Health Communications Specialist
SBIA | DDI | OCOMM | CDER

8:20 – 8:25

Session Introduction

Erin Skoda
Branch Chief (Acting)
Division of Lifecycle API
ONDP | OPQ | CDER

DAY ONE: Wednesday, March 3, 2021

8:25 – 8:55

Introduction to the DMF Review Process

The DMF review process from a timeline perspective with an emphasis on key takeaways from the workshop will be covered.

Erin Skoda
Branch Chief (Acting)
Division of Lifecycle API
ONDP | OPQ | CDER

8:55 – 9:25

Administrative Aspects of Managing a DMF

We will discuss the administrative timeline of a DMF from requesting a pre-assigned DMF number to progression of status from pending to active and subsequent submissions with advice on administrative aspects of managing a DMF.

Vathsala Selvam
Technical Information Specialist
Division of Lifecycle API
ONDP | OPQ | CDER

9:25 – 9:50

Q&A Panel

Erin Skoda, Vathsala Selvam, David Skanchy

9:50 - 10:05: BREAK

10:05 – 10:30

Managing Electronic DMF Submissions

Information to manage a DMF in eCTD format including electronic submission requirements, metrics, best practices, frequently asked questions, and where to obtain help will be covered.

Jonathan Resnick
Project Management Officer
Cloud Collaboration Capability Team
Division of Data Management Services and Solutions
Office of Business Informatics (OBI) | CDER

10:30 – 10:45

Drug Master Files from a GDUFA II User Fee Perspective

Information about DMF user fee assessment including fee requirement, payment, best practices, frequently asked questions, and where to obtain help will be covered.

Hanah Pham
Commander, USPHS
Evelyn Hong
Lieutenant Commander, USPHS
Division of User Fee Management and Budget Formulation (DUFMBF)
Office of Management (OM) | CDER

10:45 – 11:10

Timely Consult and Early Information Request (TCIR) Process for Drug Master Files (DMFs)

Background and data on the TCIR process for DMFs, which could have a substantial positive impact on the overall ANDA approval process, is discussed.

Jayani Perera
Chemist
Division of Lifecycle API
ONDP | OPQ | CDER

All times shown are Eastern (EST UTC-5)

DAY ONE: Wednesday, March 3, 2021

11:10 - 11:40

Effective Communication Strategies for Drug Master Files (DMF)

Critical pathways, modes, types, and timing of communications during the DMF and application lifecycle along with advice and best practices from an FDA perspective on maximizing the effectiveness of these communications will be covered.

David Skanchy
Commander, USPHS
Director, Division of Lifecycle API
ONDP | OPQ | CDER

Benjamin Danso
Commander, USPHS
Lead DMF Project Manager
Office of Program and Regulatory Operations (OPRO) | OPQ | CDER

11:40 - 12:00

Q&A Panel

Jonathan Resnick, Hanah Pham, Evelyn Hong, Jayani Perera, David Skanchy, Benjamin Danso

12:00 – 1:00: LUNCH BREAK

1:00 – 1:30

Poster Presentations: Responses to Submitted Questions

NOTE: Poster Presentations will be made available for viewing before the Workshop. Please visit the Workshop Event Page for information on how to view the presentations and submit questions.

Poster Presenters

1:30 – 1:35

Manufacturing Session Introduction

Erin Skoda
Branch Chief (Acting)
Division of Lifecycle API
ONDP | OPQ | CDER

1:35 – 2:00

Drug Substance Facilities – Hidden and Critical Intermediate

This presentation covers critical intermediates and how to avoid DMF hidden facilities in order to prevent delays in referencing application approvals.

Wei Liu
Senior Pharmaceutical Quality Assessor
Division of Lifecycle API
ONDP | OPQ | CDER

Cassandra Abellard
Quality Assessor/ Consumer Safety Officer
Division of Pharmaceutical Manufacturing
Office of Pharmaceutical Manufacturing Assessment (OPMA) | OPQ | CDER

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DAY ONE: Wednesday, March 3, 2021

2:00 – 2:25

ICH Q11 Q&A, a Supporting Document for the Selection and Justification of Starting Materials

This presentation will provide key concepts and clarification for starting materials selection based on ICH Q11 Q&A.

Anita Tiwari
Senior Pharmaceutical Quality Assessor
Division of Lifecycle API
ONDP | OPQ | CDER

2:25 - 2:40

Q&A Panel

Wei Liu, Cassandra Abellard, Anita Tiwari, David Skanchy

2:40 – 2:55: BREAK

2:55 – 3:20

Common Issues Related to LC and GC Methods in Type II DMFs

This presentation will focus on commonly observed issues related to LC and GC analytical procedures and validation.

Xinghua Wu
Chemist
Division of Lifecycle API
ONDP | OPQ | CDER

3:20 – 3:45

Process Validation and ICH Q7

This presentation covers manufacturing validation data from an FDA review perspective.

David Amspacher
Chemist
Division of Lifecycle API
ONDP | OPQ | CDER

3:45 – 4:10

Regulatory Considerations in Demonstrating Complex API Sameness

Regulatory strategies to show API sameness of complex APIs in generic drug product will be discussed.

Bapu R. Gaddam
Chemist
Division of Lifecycle API
ONDP | OPQ | CDER

4:10 – 4:40

Q&A Panel

Xinghua Wu, David Amspacher, Bapu R. Gaddam, David Skanchy

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DAY ONE: Wednesday, March 3, 2021

4:40 – 4:45

Day One Closing

Erin Skoda
Branch Chief (Acting)
Division of Lifecycle API
ONDP | OPQ | CDER

4:45: DAY ONE ADJOURN

DAY TWO: Thursday, March 4, 2021

8:05 – 8:15

Administrative Overview

Lisa Misevicz
Health Communications Specialist
SBIA | DDI | OCOMM | CDER

8:15 – 8:20

Welcome & Session Introduction

Ramnarayan Randad
Branch Chief
Division of Lifecycle API
ONDP | OPQ | CDER

Your SBIA Hosts for Day Two

Forest "Ray" Ford, Jr.
CAPT, USPHS, *Pharmacist*
DDI | OCOMM | CDER

Lisa Misevicz
Health Communications Specialist
SBIA | DDI | OCOMM | CDER

8:20 – 8:50

Regulatory Considerations for Impurity Qualification: ICH Q3A/Q3C/Q3D, RLD & MDD

We will present case studies on how to establish clinically relevant impurities specifications.

Hongbiao Liao
Chemist
Division of Lifecycle API
ONDP | OPQ | CDER

8:50 – 9:20

ICH M7(R1) – Chemistry and Manufacturing Control (CMC) Perspective on Hazard Assessment

This presentation outlines the key concepts surrounding hazard assessment and impurity classification per ICH M7.

Barbara O. Scott
Chemist
Division of Lifecycle API
ONDP | OPQ | CDER

9:20 – 9:45

Application of (Q)SAR and Expert Knowledge for ICH M7 Impurity Classification

The basic concepts, technical considerations, and best practices for comprehensive reporting of (Q)SAR results and common deficiencies encountered by FDA in regulatory submissions will be presented.

Naomi L. Kruhlak
Scientific Lead
Computational Toxicology Consultation Service (CTCS)
Division of Applied Regulatory Science (DARS)
Office of Translational Sciences (OTS) | CDER

9:45 – 10:15

Q&A Panel

Hongbiao Liao, Barbara O. Scott, Naomi L. Kruhlak

10:15 – 10:30: BREAK

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DAY TWO: Thursday, March 4, 2021

10:30 – 10:55

Safety Evaluation of Drug Substance Impurities in Generics

The OGD-Pharmacology/Toxicology (Pharm/Tox) process for safety evaluation of impurities in drug substances is described and illustrated with case studies, emphasizing critical elements considered in safety evaluations, and commonly occurring deficiencies in DMFs.

Chanchal Gupta
Pharmacology/Toxicology Reviewer
Division of Clinical Review (DCR)
Office of Bioequivalence (OB)
Office of Generic Drugs (OGD) | CDER

10:55 – 11:20

Nitrosamines: Where Are We Now?

We will discuss the Agency's current thinking on nitrosamine risk mitigation.

Deborah F. Johnson
Branch Chief
Division of Lifecycle API
ONDP | OPQ | CDER

11:20 – 11:50

Q&A Panel

Chanchal Gupta, Deborah F. Johnson
and **Sruthi King**
Associate Director of Pharmacology/Toxicology
Division of Clinical Review (DCR)
Office of Bioequivalence (OB) | OGD | CDER

11:50 - 12:50: LUNCH BREAK

12:50 – 1:20

Poster Presentations: Responses to Submitted Questions

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Poster Presenters

1:20 – 1:25

Life Cycle Session Introduction

Ramnarayan Randad
Branch Chief
Division of Lifecycle API
ONDP | OPQ | CDER

1:25 – 1:50

API Facility Inspections

The presentation will cover an overview of FDA's inspection program, approach to various types of inspections, recent compliance trends, and certain API-specific scenarios.

Jay Jariwala
Team Leader, Division of Drug Quality
Office of Manufacturing Quality
Office of Compliance | CDER

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DAY TWO: Thursday, March 4, 2021

1:50 – 2:15

Drug Substance Postapproval Changes Guidance: Determination of Impurity Profile Equivalence

The presentation will provide an overview of the assessment of risk factors with respect to the control of impurities and recommendations for documenting the risk-based determination.

Brian Connell
Senior Pharmaceutical Quality Assessor
Division of Lifecycle API
ONDP | OPQ | CDER

2:15 – 2:30

Q&A Panel

Jay Jariwala, Brian Connell

2:30 – 2:45: BREAK

2:45 – 3:10

Common CMC Issues in Type II DMFs and How to Avoid Them

This presentation will focus on most common quality issues in DMF submissions and briefly discuss resolution strategies and points to consider to enhance DMF submissions.

Wei Liu
Senior Pharmaceutical Quality Assessor
Division of Lifecycle API
ONDP | OPQ | CDER

3:10 – 3:35

Modernizing Drug Substance Assessment through KASA

We will discuss the current status of Knowledge-aided Assessment and Structured Application (KASA) for API.

Larisa Wu
Associate Director for Science and Communications (Acting)
ONDP | OPQ | CDER

3:35 – 4:05

Q&A Panel

Wei Liu, Larisa Wu, David Skanchy

4:05 – 4:15

Day Two Closing

David Skanchy
Commander, USPHS
Director, Division of Lifecycle API
ONDP | OPQ | CDER

4:15: ADJOURN

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